FRESENIUS KABI

Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

December 27, 2016

Mr. Mark Boyer
Associate Legal Counsel
Nebraska Department of Correctional Services
P.O. Box 94661
Lincoln, NE 68509-4661

RE: Proposed Revisions to Nebraska's Execution Protocol and Implications for Public Health

Dear Mr. Boyer:

I am writing on behalf of Fresenius Kabi, a manufacturer of injectable medicines and medical technologies that are used in hospitals across Nebraska and the United States to care for patients who have critical conditions.

I have read with interest and concern Nebraska's proposed revision to its execution protocol. Specifically, the state's plan that "the proposed, revised protocol does not identify the substance(s) to be used or the detailed method in which they will be administered" as this may have unintended public health consequences for Nebraskans and patients across the United States.

Please know that Fresenius Kabi takes no position on capital punishment. Our interest is to avoid unintended drug shortages and ensure that the lifesaving medicines we supply remain immediately available to patients – a goal I know you share.

Our concern is the potential use of certain of our products in lethal injection. This would be an improper use of these products, which are intended to save lives, and could have far-reaching negative consequences on public health due to European Union regulation 1352/2011, which prevents trade in products that could be used for capital punishment or torture. The EU has already used this regulation to ban the export of strong barbiturates and other drugs that are, or could be, used in executions. We want to avoid similar restrictions on our products as this would result in great harm to patients.

To satisfy EU concerns, Fresenius Kabi put in place distribution controls several years ago to prevent the sale or distribution of certain drugs for use in carrying out executions (see attachment). As you know, most pharmaceutical companies and their distributors have since implemented similar controls. If the EU perceives these controls to be inadequate, it could move to impose trade restrictions on needed drugs, including commonly used anesthesia drugs that doctors rely on every day in Nebraska.

EXHIBIT F

The anesthesia drug propofol, for example, is the most widely used medicine for inducing general anesthesia. It is administered more than 55 million times a year in the U.S. alone and more than 80 percent of the propofol used in the United States is manufactured in Europe. If the EU were to ban its export, it would put surgical procedures at risk nationwide.

I encourage you to speak directly to state medical associations and professional groups, especially anesthesiologists and hospitals, about the potential impact to medical and surgical care if propofol were suddenly in very short supply. Additional information can be found at www.propofol-info.com.

We have written to, and have had discussions about this with many state officials as well as the FDA and its Office of Drug Shortage, with the U.S. Department of Health and Human Services, and members of the Unites States Congress and their staffs. In 2013 I wrote to then-Governor Heinemann and others (see attachment) expressing similar concerns. To date, propofol has never been used in lethal injection.

As Nebraska works to revise its execution protocol, I am asking for your assurance that Nebraska will not use Fresenius Kabi medicines as execution agents, and that the state will not consider propofol as a lethal injection agent due to the severely negative consequences the resulting shortage would have on public health following EU sanctions.

I know we share a common goal of assuring that patients have unrestricted access to lifesaving medicines, and I would be happy to discuss this matter further with you or any Nebraska officials or provide their staffs with more information.

Sincerely,

John Ducker
President and CEO

Attachments (2)

cc: The Honorable Pete Ricketts
Governor of Nebraska
P.O. Box 94848
Lincoln, NE 68509-4848

Courtney Phillips
Chief Executive Officer
Nebraska Department of Health & Human Services
P.O. Box 95026
Lincoln, Nebraska 68509-5026

Thomas L. Williams, M.D.
Chief Medical Officer
Director of the Division of Public Health
Nebraska Department of Health & Human Services
P.O. Box 95026
Lincoln, Nebraska 68509-5026

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November 29, 2013

AUTHORIZED DISTRIBUTORS FOR RESTRICTED PRODUCTS

Effective December 1, 2013, Fresenius Kabi USA, LLC has added **rocuronium bromide** and **potassium chloride** to its Authorized Distributor program for restricted products.

The Authorized Distribution program is designed to ensure access to key drugs for patient care while preventing their sale and distribution for lethal injection.

While Fresenius Kabi takes no position on capital punishment, the company opposes the use of its products for this purpose, and therefore does not sell certain drugs to correctional facilities.

In addition to rocuronium bromide and potassium chloride, **midazolam** and **Diprivan® (propofol)** are already included in this program. Please see below for our current list of authorized distributors for restricted products.

If you have any questions, feel free to contact your distributor, or Fresenius Kabi customer service at 888-386-1300.

Drug	Authorized Distributors
Diprivan® (propofol)	• AmerisourceBergen Drug Corporation • Besse Medical, a division of ASD Specialty Healthcare, Inc. • Cardinal Health • Cesar Castillo, Inc. • DMS Pharmaceutical Group • H.C. Pharmacy Central, Inc. • H.D. Smith Wholesale Drug and Smith Medical Partners, LLC • HMPG Pharmacy • Henry Schein, Inc. • Kaiser Foundation Hospitals • McKesson Corporation • Morris and Dickson Co., LLC • Oncology Supply, a division of ASD Specialty Healthcare, Inc. • PharMEDium Services, LLC • Priority Healthcare distribution, Inc. d/b/a Curascript SD Specialty Distribution • PSS World Medical, Inc.
Midazolam	• AmerisourceBergen Drug Corporation • Cardinal Health • Cesar Castillo, Inc. • DMS Pharmaceutical Group • H.C. Pharmacy Central, Inc. • H.D. Smith Wholesale Drug and Smith Medical Partners, LLC • Henry Schein, Inc. • HMPG Pharmacy • McKesson Corporation • Morris and Dickson Co., LLC • PharMEDium Services, LLC • Priority Healthcare distribution, Inc. d/b/a Curascript SD Specialty Distribution
Potassium Chloride	• AmerisourceBergen Drug Corporation • Cardinal Health • Cesar Castillo, Inc. • DMS Pharmaceutical Group • H.C. Pharmacy Central, Inc. • H.D. Smith Wholesale Drug and Smith Medical Partners, LLC • HMPG Pharmacy • McKesson Corporation • Morris and Dickson Co., LLC • Oncology Supply, a division of ASD Specialty Healthcare, Inc. • PharMEDium Services, LLC

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Drug	Authorized Distributors
Rocuronium Bromide	• AmerisourceBergen Drug Corporation • Cardinal Health • Cesar Castillo, Inc. • DMS Pharmaceutical Group • H.C. Pharmacy Central, Inc. • H.D. Smith Wholesale Drug and Smith Medical Partners, LLC • HMPG Pharmacy • McKesson Corporation • Morris and Dickson Co., LLC • PharMEDium Services, LLC

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December 23, 2013

The Honorable Dave Heineman
Governor of Nebraska
Office of the Governor
P.O. Box 94848
Lincoln, Nebraska 68509-4848

Choosing a Lethal Injection Protocol
Propofol and Implications for Public Health

Dear Governor Heineman:

I read with interest a recent news article in the *Lincoln Journal Star* that Nebraska, like other states, is considering changing its lethal injection protocol because its supply of sodium thiopental is expiring and the drug is unavailable for capital punishment.

I wrote to you in September about the drug Propofol and why it shouldn't be used for lethal injection. Since I haven't received a response, I would like to take the opportunity to remind you about this important matter that impacts the public health of Nebraskans and patients across the United States. I am copying Attorney General Jon Bruning and Director of Correctional Services Michael Kenney, as well as officials at HHS and FDA who have been involved in this issue and have an ongoing interest in drug shortages.

Fresenius Kabi USA is the U.S. arm of a European company that specializes in medicines and technologies – including injectable drugs like Propofol – used in hospitals and clinics across Nebraska and the United States.

Propofol is an anesthetic used widely in surgeries to induce general anesthesia. It is administered more than 50 million times a year in the United States. To our knowledge, this drug has never been used in an execution anywhere. In the United States, hospitals and anesthesiologists have been vocal in opposing the use of Propofol in lethal injection, as this would result in a shortage that would harm patients and physicians nationwide.

At issue is European Union regulation 1352/2011, which prevents trade in products that could be used for capital punishment or torture. It is because of this regulation that drugs such as sodium thiopental, which were previously used in lethal injection, are now in short supply, or virtually unavailable in the United States. The EU can be expected to add

Propofol to its list of trade-restricted products if the drug is used in an execution. More than 85 percent of Propofol used in the United States is manufactured in Europe. The result would be a severe and harmful shortage of Propofol affecting millions of patients. You and your staff can learn more about this issue at an informational web site we created: www.propofol-info.com.

You may be aware that state of Missouri considered using Propofol in an execution earlier this year. It decided against this following the objections of physicians, hospitals, medical and public interest groups, and drug manufacturers including Fresenius Kabi. By choosing a different drug, Missouri Governor Jay Nixon successfully avoided a public health crisis.

Please know that Fresenius Kabi takes no position on capital punishment. We are deeply sympathetic to the victims of violent crime. We are, however, extremely concerned about the harm to patient care that a shortage of Propofol would cause.

We therefore respectfully request that you exclude Propofol from your execution plans. I encourage you to speak directly to your state medical associations and professional groups, especially anesthesiologists and hospitals, about the potential impact to medical and surgical care if Propofol were in short supply.

We have written to, and have had discussions about this issue with many state officials as well as the FDA and its Office of Drug Shortage, with the U.S. Department of Health and Human Services, and with many members of Congress and their staffs.

The clinical and safety profile of Propofol make it a drug of choice that contributes to the care of millions of patients every year. We are asking for your commitment to protect patients by not permitting Propofol to be used in lethal injection.

I would be happy to discuss this matter with you further, or to provide you or your staff with more information. I greatly appreciate your leadership in this matter, and I look forward to hearing from you.

Sincerely,

John Ducker
President and CEO

cc: Jon Bruning, Attorney General, State of Nebraska
Office of the Attorney General,

Michael Kenney, Director, Nebraska Department of Correctional Services

The Honorable Margaret A. Hamburg, M.D., Commissioner,
U.S. Food and Drug Administration

Sally Howard, J.D., FDA Deputy Commissioner for Policy Planning and Legislation

Lisa Barclay, J.D., Chief of Staff, U.S. Food and Drug Administration

Capt. Valerie Jensen, R.Ph., Associate Director, Drug Shortages Program,
Center for Drug Evaluation and Research, U.S. Food and Drug Administration

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September 25, 2013

The Honorable Dave Heinemann
Governor of Nebraska
State Capitol
Second Floor NE
Lincoln, NE 68509-4848

Propofol and Lethal Injection – Implications for Public Health

Dear Governor Heinemann:

I am writing on behalf of Fresenius Kabi. We are a manufacturer of injectable medicines and medical technologies that are used in hospitals across Nebraska and the United States to care for patients who have critical conditions.

We are aware that some states are considering changes to their lethal injection protocols, because certain drugs have become unavailable due largely to European Union regulation 1352/2011, which prevents trade in products that could be used for capital punishment or torture.

As it has already done with barbiturates, the EU has stated it will add Propofol, a drug we manufacture, to its list of trade-restricted products if the drug is used in an execution. The result of this would be a severe and harmful shortage of Propofol affecting patients and medical professionals across the United States. More than 85 percent of Propofol used in the United States is manufactured in Europe. Propofol is the most widely used medicine for inducing general anesthesia. It is administered more than 50 million times a year in the United States alone.

Please know that Fresenius Kabi takes no position on capital punishment. We are deeply concerned, however, about the potential harm to patient care that a shortage of Propofol would cause.

We therefore respectfully request that you exclude Propofol from your execution plans. To help professionals learn more about this issue, we created an informational web site (www.propofol-

info.com) that includes links and background that might be helpful to you and your staff. In addition, I encourage you to speak directly to state medical associations and professional groups, especially anesthesiologists and hospitals, about the potential impact to medical and surgical care if Propofol were suddenly in very short supply.

We have written to, and have had discussions about this with many state officials as well as the FDA and its Office of Drug Shortage, with the U.S. Department of Health and Human Services, and with members of Congress and their staffs.

The clinical and safety profile of Propofol make it a drug of choice that contributes to the care of millions of patients every year. We are asking for your commitment to protect patients by not permitting Propofol to be used in lethal injection.

I would be happy to discuss this matter further with you, or to provide you or your staff with more information. Please don't hesitate to contact me to discuss this important issue. I greatly appreciate your leadership in this matter.

Sincerely,

John Ducker
President and CEO

cc: The Honorable Kathleen Sibelius, Secretary, Health and Human Services
The Honorable Margaret A. Hamburg, M.D., Commissioner, U.S. Food and Drug Administration
Sally Howard, J.D., FDA Deputy Commissioner for Policy Planning and Legislation
Lisa Barclay, J.D., Chief of Staff, U.S. Food and Drug Administration
Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research
Capt. Valerie Jensen, R.Ph., Associate Director, Drug Shortages Program, Center for Drug Evaluation and Research, U.S. Food and Drug Administration